

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

AVENTIS PHARMACEUTICALS INC. and  
SANOFI-AVENTIS US LLC,

Plaintiffs,

V.

BARR LABORATORIES, INC.

Defendant.

**REDACTED PUBLIC VERSION**

C.A. No. 06-286 (GMS)

**BARR LABORATORIES INC.'S REPLY  
IN SUPPORT OF ITS MOTION *IN LIMINE* TO EXCLUDE  
AVENTIS' ASSERTIONS OF ANY INVENTION DATES LATER THAN MAY 1, 1992**

Dated: May 5, 2008

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### ARGUMENT

Aventis' response brief makes clear that it has no legitimate justification for attempting to change the entire landscape of this case, only weeks before trial. Aventis concedes that it did not discover any new facts and even argues that "Barr has had the relevant facts all along." (Resp. at 1, 4-5.) (D.I. 182.) It also does not deny that it had the burden of proof on the experimental use exception. And it never disputes that Barr fully answered its interrogatory calling for "all facts and evidence" about Barr's invalidity contentions. (Barr Mot. at 5; Ex. 5 at 14.) (D.I. 180.)

Despite all this, Aventis argues that it is entitled to enormously prejudice Barr and potentially derail a long-scheduled trial because Aventis – and nobody else – allegedly made two legal mistakes. First, Aventis asserts that it had been unaware that the experimental use exception is inapplicable after reduction to practice, despite the fact that this has been settled law since at least 1989. (D.I. 161 at ¶ 370.) Second, Aventis claims it was unaware of the applicable law on reduction to practice, despite the fact that the Federal Circuit has not changed the standard for reduction to practice for literally decades.

Notwithstanding its efforts to blame *Barr* for its alleged legal mistakes, Barr obviously had no duty to provide legal advice to Aventis' highly-qualified lawyers, who are from a top-notch Chicago law firm that specializes in patent litigation. (See <http://www.mbhb.com>.) Aventis had a duty to conduct its *own* legal analysis and to prosecute its case according to its *own* view of the law.

In an effort to justify its eleventh-hour change of position, Aventis claims that it only recently realized that its 1992 reduction-to-practice date made the experimental use exception inapplicable. But, in fact, Aventis had a duty to honestly disclose its reduction-to-practice date *regardless* of the legal consequences of that truthful disclosure. And unlike its belatedly-asserted 1994 date, Aventis' originally-asserted 1992 date was accurate.

Under the law, a claimed invention is reduced to practice as soon as one with ordinary skill would conclude that the invention will “work for its intended purpose.” *Slip Track Sys., Inv. v. Meta-Lite, Inc.*, 304 F.3d 1256, 1265 (Fed. Cir. 2002); *Winter v. Lebourg*, 394 F.2d 575, 581 (C.C.P.A. 1968). Here, Aventis’ active ingredient had been tested and FDA-approved for use in literally dozens of products, including a nasal spray to treat allergic rhinitis using the exact same dosing regimen. (See D.I. 161 at ¶¶ 17-19, 31-34.) Thus, Aventis established Nasacort would work for “its intended purpose” as soon as it developed a nasal spray that would permit the active ingredient to physically reach the nasal cavity. That happened in March 1992, when Aventis finalized the Nasacort AQ formulation.

To attempt to now justify a two-year shift in that date, Aventis cites *In re Omeprazole Patent Litigation*, 490 F. Supp. 2d 381, 392, 506-07 (S.D.N.Y. 2007). But that case was decided nearly a year ago in May 2007 and, thus, cannot justify Aventis’ shift in position only weeks before trial. *Omeprazole* is also completely irrelevant. That case involved the claimed special formulation of an active ingredient that was “very difficult to formulate” and was “exceptionally” sensitive to stomach acids. *Id.* Clinical trials with an old formulation, which the defendant argued established reduction to practice, had *failed* due to that sensitivity. *Id.* at 506 n.98. The district court thus held that extensive human clinical trials were necessary for reduction to practice of the new formulation. *Id.* at 506-07. That was arguably reasonable under the unique circumstances of that case. Clinical trials were the only way to establish that the new formulation could survive stomach acids and, thus, reach the blood system in sufficient quantities to be effective. *Id.* Here, in sharp contrast, Aventis’ claimed invention involves an already-approved active ingredient at the already-approved dose using the same formulation as another already-approved nasal product. (D.I. 161 at ¶¶ 17-19, 31-34.)

Aventis also cannot seriously dispute that Barr would suffer enormous prejudice from Aventis' eve-of-trial assertion of a brand new reduction-to-practice date. Aventis implies that Barr is somehow responsible for any failure to take discovery on that new assertion. This makes no sense. Barr could not possibly have investigated an April 1994 reduction-to-practice date that had not been asserted. Nor was Barr required to take fact discovery and develop expert testimony to confirm that Aventis told the truth when asserting a 1992 reduction-to-practice date.

For the same reasons, it is nonsense to suggest that "limited additional depositions" that would not delay the trial would cure Barr's prejudice. As Barr has already explained, a *two-year* shift in reduction to practice would not only require more depositions on the state of mind of the Nasacort AQ formulators and clinical investigators, it would open entirely new areas of discovery on diligence, new prior art, and expert opinions. (Barr Mot. at 2-3.) (D.I. 180.)

Finally, Aventis has not cited a single case supporting its position that it should be permitted to belatedly change its position on a fundamental issue based on a claimed ignorance of the law. None of Aventis' cases involved a belated disclosure by a sophisticated party represented by competent counsel claiming a legal mistake. *Eng'd Prods. Co. v. Donaldson Co.*, 165 F. Supp. 2d 836, 857-860 (N.D. Iowa 2001) (permitting supplementation based on factual mistake discovered when other party asserted 102(b) defense for the first time); *Prins v. ITT Corp.*, 757 F. Supp. 87, 94-95 (D.D.C. 1991) (permitting employee plaintiff to supplement based on misinterpretation of interrogatory). And, contrary to its suggestion, a showing that Aventis acted in bad faith is not required to preclude Aventis' belated supplementation. (See Barr Mot. at 1-2 (citing four Third Circuit cases excluding belatedly disclosed evidence due to prejudice despite no showing of bad faith).) Thus, the Court should grant Barr's motion.

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May 5, 2008

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**CERTIFICATE OF SERVICE**

I, Karen L. Pascale, Esquire, hereby certify that on May 12, 2008, I caused to be electronically filed a true and correct copy of the foregoing document, ***Barr Laboratories Inc.'s Motion in Limine to Exclude Aventis' Assertions of Any Invention Dates Later Than May 1, 1992***, with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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I further certify that on May 12, 2008, I caused a copy of the foregoing document to be served by e-mail on the above-listed counsel and on the following non-registered participants in the manner indicated:

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